

REMARKS

In this Response, Applicant cancels claim 16, and addresses the Examiner's rejections based on the claims previously pending. Also, a Rule 132 declaration of Ing. Erhard Frey is submitted to identify the preparation condition for the comparison sample papaya puree used in Dr. Wutschitz comparison tests, of which results were submitted as a declaration in September 23, 2009. Reconsideration of the application in view of the following remarks is respectfully requested.

Interview Summary

Applicant acknowledges with appreciation the courtesy extended by the Examiner during the formal interview with the undersigned attorney on August 13, 2010. During the interview, the undersigned attorney and the Examiner discussed the outstanding rejections over the Wolff reference (U.S. Patent No. 4,089,985) in view of Swensen (U.S. Patent No. 5,840,356), and in particular, the meaning of the term "cooking." Also, the preparation conditions used to prepare the comparison sample in Dr. Wutschitz declaration was also discussed. No agreement was reached regarding the allowance of any claims.

35 USC 1.132 Declaration

The Examiner found the declaration of Dr. Christa Wutschitz and accompanied results not persuasive because the results of the study were obtained by comparing "a generic uncooked bottled papaya product" and thus the declaration is not commensurate in scope with the invention.

Applicant respectfully disagree. The comparison sample was not a generic uncooked bottled papaya. As the declaration states, the comparison sample was also pasteurized. See Exhibit A, p. 1-2. ("Papaya pulp (P): tree ripened fruit were picked, peeled, deseeded and then pureed. In order to reduce the pH-value citric acid was added (same procedure as Caricol). The customary papaya fruit pulp was filled into bottles and pasteurized." (emphasis added)) The

detailed conditions for the pasteurization is hereby submitted by the accompanying declaration of Mr. Ing. Erhard Frey, who is the CEO of Frey Delikatessen GmbH, an Austria company manufacturing Caricol according the present invention. Mr. Frey has personal knowledge of the comparison tests conducted by Dr. Christa Wutschitz and discussed in his September 16, 2009 declaration. The conditions are as follows:

The reference papaya pulp (P) was picked, peeled, deseeded and pureed, and after the citric acid was added, the papaya pulp was bottled and pasteurized. The pasteurization was conducted by heating the bottled papaya pulp (P) for around 20 minutes at 90 °C and letting it cool down to room temperature for a further 20 minutes.

The Frey Dec., # 3.

Rejections under 35 USC §103

In the final Office Action, the Examiner has maintained all the obviousness rejections issued in the previous non-final Office Action (dated April 2, 2009). Applicant respectfully traverses all of these rejections.

(A) Rejections of claims 1-3, 5-7, 15-16, and 18-19 over U.S. Patent No. 4,089,985 to Wolff ("Wolff")

The Examiner relies on a rationale that varying the temperature of cooking papaya is well within a person of ordinary skill in the art based on the teaching of Wolff. In addition, in *Response to Arguments* section of the Office Action, the Examiner cites a Webster's Dictionary definition for "cook" as "to prepare food by the action of heat", and asserts that the high speed blending in Wolff's process would be considered "cooking." Applicant disagrees.

Wolff discloses a method for producing a papaya juice product, including blending papaya at high speed and raise the temperature of the papaya during the blending. However, Wolff at least does not disclose or suggest *cooking* papaya fruits *for at least 30 minutes*.

First, Applicant clarifies that the term "cooking" in the claims should be understood as "cooking at a boiling condition," and disagrees with the Examiner's interpretation of "cooking" in the claims as simply "applying heat." Also, "cooking" is conducted in an aqueous medium. See, e.g., Example 1. As the boiling point of water is 100 °C, the cooking condition should be

100 °C or close thereto. A claim should be understood in view of intrinsic evidence. *Philips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005). As this response would become a part of the intrinsic evidence, one of skill in the art would understand that the terms “cook” and “cooking” in the specification and claims are used to mean boiling.

With this understanding of the word “cook” (or “cooking”) in the present application, it is clear that the total period of time the papaya in Wolff is subjected to the cooking temperature is significantly less harsh condition than those recited in the claims. First, Wolff teaches away heating the puree excessively. Wolff states,

The minimum length of time required for pasteurizing at any particular temperature is inversely proportional to temperature. Thus pasteurization of papaya juice requires holding it at a temperature of 149 °F (65°C) for a minimum of 30 minutes; 7 to 10 minutes at 165 °F (74 °C); 4 to 5 minutes at 175 °F (79°C) or 1 to 2 minutes at 195 °F (91°C).

Col. 5, lines 5-11. (emphasis added).

Second, Wolff discloses high speed blending within a temperature range of 195 to 210 °F (91-99°C), of which the duration is at most 18 minutes. As disclosed in col. 2, lines 13-28, col. 3, lines 18-31, and claim 1 of Wolff, Wolff’s process includes at least *18 minutes* of high speed blending, which can be roughly divided into 3 stages: (1) raising the temperature of the papaya meet *to* about 91°C (this stage takes about 10 minutes); (2) maintaining the temperature at 91°C for 3 minutes, with the blender container covered; and (3) continuing the high speed blending for 5 minutes with the blender container uncovered. This condition is similar as the condition used to prepare the comparison sample (i.e., pasteurized at 90 °C for 20 min.) used in Dr. Wutschitz’s tests yet different from the claimed method. Thus, the comparison tests conducted by Dr. Wutschitz would effectively provide unexpected result of the product prepared by according to the presently claimed method.

As previously discussed in our response filed on September 23, 2009 and accompanied declaration of Dr. Wutschitz, the papaya puree prepared according to the presently claimed method showed surprising and significant efficacy in treating a gastroenterological condition compared to a papaya pulp prepared under the similar condition as disclosed in Wolff. Thus, the

comparison test effectively demonstrates that the presently claimed method have an unexpected result over the process disclosed in Wolff.

The Examiner may argue that one of skill in the art can easily increase the heating time in the Wolff process (i.e., 18 min) to that of the claimed invention (i.e., at least 30 minutes). However, the obviousness test is not whether one can easily do or not. Rather, one of skill in the art with a reasonable creativity has any reason to modify the cited prior art to reach the claimed invention. It is common sense that heating longer time would increase manufacturing cost and that many other healthy nutrients like vitamins are heat sensitive. Without foreseeing any benefit of heating longer time than what Wolff teaches, no one of skill in the art would be motivated to go beyond what is disclosed in Wolff. Here, no such benefit is disclosed in Wolff. In fact, Wolff teaches heat for less time at higher temperature. Without any teaching of such benefit, the argument of obviousness over Wolff is a mere improper hindsight argument.

Based on the above reasons, Applicant submits that independent claim 1 is not obvious over Wolff. As all the other claims under this rejection depend from claim 1, they are not obvious over Wolff for at least the same reasons. However, for a complete response, Applicant briefly addresses the Examiner's rejections as follows.

(B) Rejections of claim 4 over Wolff in view of U.S. Patent No. 5,840,356 to Swensen
("Swensen")

Swensen does not cure the deficiency of Wolff. It does not teach or suggest heating high and longer than what is disclosed in Wolff would provide any benefit offsetting the downside of higher cost and potential damages on other nutrients. Accordingly, Applicant submits that for at least the above reason with regard to Wolff, and for Swensen's failure to cure the deficiency of Wolff regarding the cooking step, independent claim 1 and its dependant claims are not obvious over Wolff in view of Swensen.

(C) Rejections of claims 8-14 over Wolff in view of Dawson, Chandalia, and Imao

The comparison sample prepared according to a similar condition as Wolff clearly did not show the high therapeutic effectiveness of the product prepared by the claimed process. See Wutschitz declaration, Exhibit A. Accordingly, treating digestive disorder using a papaya puree prepared by the process of claim 1 has an unexpected result and is not obvious.

(D) Rejections of claims 17-20 over Wolff in view of JP 08056562 to Nakayama
("Nakayama")

Claims 17-20 depend from claim 15, which in turn depends from claim 1. Since claim 1 has been shown as not being obvious over Wolff as discussed above, and Nakayama does not cure the deficiency of Wolff (the Examiner's reliance on Nakayama only pertains to Nakayama's teaching with regard to the sugar content of a papaya product), claim 1 and its dependant claims cannot be rendered obvious by the combination of Wolff and Nakayama.

Based on the foregoing, Applicant respectfully requests that all rejections under 35 U.S.C. 103(a) be withdrawn.

Conclusion

In view of the above remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue. If any of the pending claims are not deemed allowable, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

If any fees are due in connection with this response or any overpayment has been made, the Director is hereby authorized to charge such fees and to credit any overpayment to Deposit Account No. 02-4377.

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Respectfully submitted,



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